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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,218	06/27/2003	Vincent Ling	GNN-010CPDV	7566
959	7590	06/23/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,218	LING ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1 - 15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

2. Prior to setting forth a restriction requirement, the following is noted: The claims contain multiple informalities, at least in claims 1 ("one ore more"), 4 ("ICOS"), and 13 ("molelcule"). Proofreading of the claims and appropriate correction is required.

Restriction Requirement

3. It is noted that claims 1, 5, and 9, and dependent claims thereof, recite two types of methods: those directed at mRNA and those directed at protein. These methods are mutually exclusive in that they reach separate and distinct endpoints, and in that they employ unrelated steps to accomplish these mutually exclusive endpoints. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I: Claims 1 – 8 and 13 – 15, drawn to methods for determining the mRNA levels of one or more molecules associated with evaluation of risk and diagnosis of spontaneous abortion, classified in Class 435, subclass 6.

Group II: Claims 1 – 8 and 13 – 15, drawn to methods for determining the protein levels of one or more molecules associated with evaluation of risk and diagnosis of spontaneous abortion, classified in Class 435, subclass 7.1.

Group III: Claims 1 – 8 and 13 – 15, drawn to methods for determining the mRNA levels of one or more molecules associated with evaluation of treatment of spontaneous abortion, classified in Class 435, subclass 6.

Group IV: Claims 1 – 8 and 13 – 15, drawn to methods for determining the protein levels of one or more molecules associated with evaluation of treatment of spontaneous abortion, classified in Class 435, subclass 7.1.

5. Groups I, II, III, and IV are different methods. A method of detecting mRNA and protein differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct. A method for evaluating the risk and diagnosis of a condition and a method of evaluating treatment of a condition differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be

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required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

7. Applicant is invited to amend the claims or provide new claims which read on each Group I – IV separately.

In addition, Applicant is invited to recite clear, distinct and positive process steps with a step that clearly relates to the preamble of the claims of detecting mRNA or polypeptides.

Species Election

8. This application contains claims directed to patentably distinct species of the claimed inventions I – IV, wherein the presence of one or more of the following is detected:

- a) VCAM,
- b) P-selectin,
- c) E-selectin,
- d) IL-2,
- e) IL-10,

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- f) IL-12,
- g) IL-11,
- h) $\text{TNF}\alpha$,
- i) IL-1 β ,
- j) TGF,
- k) RANTES,
- l) IL-6,
- m) IFN- γ ,
- n) B7.1,
- o) B7.2,
- p) CD4,
- q) CD8,
- r) GL50,
- s) ICOS.

Each species differs with respect to their physicochemical properties; therefore, they are patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 5, and 9, for example, are generic.

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9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

June 17, 2004


PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER

6/17/04